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TEN YEARS AFTER THE IMPLEMENTATION OF DSHEA: THE STATUS OF DIETARY SUPPLEMENTS IN THE UNITED STATES

STATEMENT OF

ALAN DUMOFF, J.D., M.S.W.
AMERICAN ASSOCIATION FOR HEALTH FREEDOM

BEFORE THE SUBCOMMITTEE ON HUMAN RIGHTS AND WELLNESS
COMMITTEE ON GOVERNMENT REFORM
US HOUSE OF REPRESENTATIVES

MARCH 24, 2004

Mr. Chairman and members of the committee, my name is Alan Dumoff and I am here on behalf of the American Association for Health Freedom (AAHF). We appreciate the opportunity to present our views on the implementation of the Dietary Supplement Health Education Act (DSHEA), and status of supplements ten years after its enactment.

We would also like to take this opportunity to thank the Chairman for his sponsorship and active support for H.R. 2085, the Access To Medical Treatment Act. This is legislation that we strongly care about.

The AAHF is composed of medical practioners, small distributors, and average Americans dedicated to ensuring medical choice freedoms and access to the full range of health promotion and medical treatment options. The organization works with other groups to achieve a health care system at the federal and state levels of government in which practitioners and citizens can freely use integrative medical therapies, including dietary supplements, without fear of recrimination, with the well being of patients foremost in mind.

Our physician members are seeing more and more patients seeking professional help with incorporating integrative complementary and alternative medical (CAM) treatment options, including the use of dietary supplements, into their lifestyles, and as medical treatment options for diseases or terminal illnesses for which conventional medical treatments have not worked. It is well recognized that there are 158 million consumers of dietary supplements in our country. Estimates also show that frustrated by the inability of mainstream medicine to meet all their health care expectations and needs, as many as 42 percent of Americans are adopting integrative medicine approaches to satisfy their health care needs.

Since enactment of DSHEA, and its subsequent execution by the Food and Drug Administration (FDA), the AAHF has had the opportunity to testify on DSHEA implementation issues that you, Mr. Chairman, have already been willing to address. The AAHF has played a major role in trying to ensure that FDA regulatory interpretations and decisions comply with the Congressional intent for the DSHEA. Aside from the normal regulatory participation avenues, the AAHF has, unfortunately, been compelled to go the route of federal judicial action, starting with *Pearson v. Shalala,* 64 F.3d 650 (D.C. Cir. 1999). Since the successful outcome with *Pearson*, we have also been compelled and have been successful in challenging the FDA's interpretation of allowed health claims for dietary supplements in a number of other DSHEA related federal suits. In general, these federal actions have been motivated by the FDA's efforts to limit the reach of *Pearson*, and refusal to recognize the changing scientific evidence and public demand for access to the therapeutic benefits of dietary supplements.

There have been many bumps in the road over the past ten years with the implementation of DSHEA. In our view, the FDA's intrinsic resistance to implementing the federal regulatory framework created by the DSHEA still requires the continuing oversight of the Congress. Medical practitioners and consumers are still wondering if the FDA has accepted the public's reasonable desire and the clear mandate of Congress that consumers have access to health information regarding dietary supplements. In our view, the answer too often has been no.

This is not to say that all of the FDA's DSHEA implementation actions have been misdirected. The enforcement mechanisms for ensuring the public safety of dietary supplements, available to the FDA under the DSHEA, for the most part, have and are working. There are three specific and one broad implementation matters we believe deserve the committee's attention. These may be candidates for future committee oversight or Congressional action. These are briefly discussed as follows.

Proposed FDA Good Manufacturing Practices Regulation

We support having a Good Manufacturing Practices (GMP) regulation on the books. After ten years, we would have hoped that consumers could have confidence that what's on the label is what's in the bottle. The FDA's effort to apply pharmaceutical standards to the supplement industry has delayed meeting this critical goal. As the FDA moves toward implementing GMPs, our concern is its severe impact on small manufacturers and distributors, who cannot bear these overly stringent and unnecessary requirements. The FDA's regulatory proposal does grant a three-year implementation period for small companies. However, the proposed mandated requirements, no matter how long the period is for a transition, are ones that many of our small distributor members simply cannot financially afford. Many of these provide specialty products that are simply unavailable from any other source. The FDA is essentially proposing to impose a pharmaceutical drug GMP model on small dietary supplement manufacturers and distributors. Options such as limiting the proposed GMP requirements to companies that produce high-risk products need to be explored further. The chilling effect of excessive FDA regulation would not only affects consumer access to supplements but also, in this case, lost jobs for hundreds if not thousands of Americans.

Federal Trade Commission Requirements Run Counter to the DSHEA

The responsibility for ensuring the validity of dietary supplement health claims under DSHEA rests with the FDA. Yet the FTC has actively imposed its own views about what health statements may be made in certain non-manufacturer sponsored commercial advertising venues that have included dietary supplements. While we recognize that the FTC has a legitimate role to play in preventing misleading advertising, the standards applied by the FTC are, however, sufficiently different from the scheme Congress intended in enacting the DSHEA. These actions have and are creating

confusion among manufacturers and representatives, and with commercial broadcasters, about what claims may be made. On the other hand, recent actions taken against the marketers of "Focus Factor," a dietary supplement purported to improve concentration, "V-Factor", a supplement purported to enhance sexual performance, and marketers of "Seasilver", a supplement purported to be clinically proven to treat or cure 650 diseases, including cancer and AIDS, in consumer "infomercials" should be applauded.

But, the standards imposed in these actions have set forth levels of scientific evidence, to the point that manufacturers are required to produce multi-center studies in which their product was used, rather than studies supporting the generic ingredients upon which they are based. There is no scientific basis for such requirements and the impression these actions give is that FTC is attempting, not just to regulate advertising, but also to regulate the content of information that can be available to consumers of dietary supplements. This is contrary to the intent of Congress that the industry be regulated under the standards of DSHEA. Dietary supplement manufacturers that meet the standards of evidence worked out over years of Congressional and judicial action should not have to meet an additional, and uncertain, burden placed upon them by the FTC. The result of this co-agency implementation problem has had a serious impact on helping to educate consumers.

The Struggle of the FDA to Properly Implement Qualified Health Claims Under *Pearson*

The FDA's response to the requirement in the *Pearson* case to develop a reasonable approach to qualified health claims occurred a year after the mandate. The interim approach has not been adequate to assess and inform consumers about the level of scientific support for a claim. There are two significant problems with the current interim FDA approach: (1) the FDA reviewers do not have the specialized expertise in the fields of botanical, herbal, and nutritional medicine to fairly and efficiently evaluate

claims; and (2) the juxtaposition of the manufacturer's claim with the FDA disclaimer creates a label that appears "bipolar", reflecting the schism in the politics of dietary supplements rather than useful information for the consumer.

For example, with regard to scientific review, there are numerous claims, such as saw palmetto in the treatment of benign prostatic hypertropthy (BPH), for which the evidence is very clear to experts in the field. But while the FDA review panel members are respected in their scientific endeavors, they lack the expertise in the area to recognize this. The FDA should seek the expertise of those with specific knowledge about these issues to expedite a knowledgeable review of the claims.

Secondly, glowing claims by manufacturers set next to language that "very limited and preliminary scientific research suggests . . . there is little scientific evidence for this claim" does not provide useful consumer information. Under a proposed FDA regulation, the agency is seeking to establish an "evidence-based ranking system." Under this system, the agency would review the science submitted in support of a claim, assesses the science and rank structure and function claims with a letter (A, B, C, or D) corresponding to the level of support for a supplement health claim. While this sounds promising, we continue to have concerns with the "evidenced based" approach being propositioned. In comments filed by the Federal Trade Commission (FTC) with the FDA on this proposed rule, the FTC's own consumer research suggested that consumers could distinguish between levels of scientific support for health claims. We are concerned and suggest that the inclusion of scientists experienced in the level of research could better evaluate and tailor decisions and language that would be useful to consumers.

Regulating Supplements Like Prescription Drugs

Taking a forward looking public policy point of view, we have had and continue to have concerns with the prevailing overall FDA regulatory philosophy toward dietary supplements. Almost since the beginning of DSHEA, the policy and legal positions of the FDA have been to regulate supplements more like prescription drugs. We are opposed to any FDA regulatory or Congressional legislative proposals to substantially change, if not repeal, DSHEA in this fashion. Doing so goes against the original intent of DSHEA. Doing so would lead to higher costs for consumers and/or patients wanting to help reduce health care costs by their own taking of responsibility for improving their health status and/or using less expensive and equally effective complementary and alternative integrative medical treatment options.

Adopting this approach, either by federal administrative law or via federal legislation is not needed. Under one pending Congressional bill, H.R. 3377, our analysis shows that two-thirds of current dietary supplement products could be subject to FDA prescription drug like regulation. If enacted, it could effectively repeal two-thirds of the DSHEA. To paraphrase a slogan used on a civil rights discrimination issue during the Clinton Administration, there may be implementation problems with DSHEA, but Congress should “Amend it, and not end it”.

Finally, when I was asked to testify, I recalled an incredible experience I had at a meeting co-sponsored by the World Health Organization (WHO) at a conference on integrative medicine. I discovered that many of the international speakers addressed methods of restricting access to dietary supplements. I took the opportunity to describe the history of efforts by the FDA to restrict reasonable access to dietary supplements - restrictions rejected by U.S. consumers who have clearly voiced their desire to make their own choices in this regard. These voices have been heeded by Congress in the DSHEA. It is important that we remember and maintain the important

choice for health freedom that the DSHEA represents, and how it reflects the U.S. experiment in freedom that is unique in the world.

Ten years after DSHEA, the law has, in our view, greatly benefited millions of Americans who use supplements on a regular basis, and Americans seeking professional help with integrating complementary and alternative medical treatment options, including the use of dietary supplements, into their lifestyles and as part of medical treatment options. We realize that these are complex issues. We believe that they deserve consideration in light of all of the known and published scientific evidence and advances taking place in the day-to-day use of integrative medical treatment alternatives and growing public demand.

Again, thank you for the opportunity to express our views on DSHEA implementation. We hope that we have been able to highlight our public policy concerns. I would welcome any questions members of the committee may have.

ALAN DUMOFF

Doctor of Law
Master of Social Work

Curriculum Vita

Health care attorney with extensive experience on matters of law, practice management, program design and clinical delivery offering consultations to institutional providers and complementary practitioners developing integrative health care programs.

Professional Roles:

Attorney
Lobbyist
Consultant
Author
Mediator
Psychotherapist

Clientele:

Physicians
CAM Practitioners
Integrated Clinics
National Policy Organizations
Professional Assoc.
Dietary Supplement Manufacturers
Medical device Manufacturers
Patients

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SUMMARY

Legal Practice–Fifteen years of experience focusing on legal issues arising within complementary and alternative medicine ("CAM"). Attorney in solo practice bringing a broad range of skills to bear on practice since 1988. In-depth understanding of CAM practice and its regulation, including medical board discipline, food, drugs, devices and dietary supplements, Medicare/insurance reimbursement, laboratory requirements and other regulatory matters; practice and risk management. Representation before U.S. Supreme Court, extensive appellate and administrative experience.

Consulting–Consultations on a wide range of legal, management, business and clinical aspects of integrative/CAM practice.

Lobbying–National and state lobbying and drafting of legislative solutions to problems in integrative health care delivery.

Public Policy Leadership – Former Executive Director of CAM national board certification body; extensive volunteer role in and contributions to national collaborative efforts working toward integrative health care public policy.

Extensive Publications/Presentations–Over 50 articles, anthology chapters, and conference presentations on integrative health care topics, including co-chair of two national CAM conferences and an international presentation, addressing a wide variety of legal and policy issues regarding integrative/CAM practice.

Clinical/Program Design Skills–Well-rounded care delivery experience, including facilitation of a multidisciplinary health care team, seven years delivering family therapy/psychotherapy services to over 500 families, several years assisting in design and management of social programs, and post-graduate training in research design.

LEGAL SKILLS

Notable Achievements:

- United States Supreme Court, Counsel on *Hercules v. United States*, 516 U.S. 417 (1996), *sub nom. Wm.Thompson v. United States*, 26 Cl. Ct. 17 (1992), *aff'd* 24 F.3d 188 (Fed. Cir. 1994); drafted successful petition for certiorari in government contract matter involving Agent Orange damages arising from Vietnam war.
- Obtained reversal of FDA position barring sale of Shealy Relaxmate™ as an unapproved medical device.
- Successful criminal appellate practice; obtained reversal of criminal conviction–*Jones v. Unites States*, 779 A.2d 357 (D.C. 2001) due to coercive statements to the jury from the bench, remand for hearing in *Haley v. United States*, 799 A.2d 1201 (D.C. 2002), and release of client from prison in *Lawrence v. United States,* F-7791-89.

Other Published Opinions:

- *Faulkenstein v. Board of Medicine*, 727 A.2d 302 (D.C. 1999).
- *Hall v. Henderson*, 627 A.2d 1047 (D.C. 1996).
- *Singer v. D.C. Board of Medicine*, 631 A.2d 1232 (D.C. 1993).
- *Weaver v. Grafio*, 595 A.2d 983 (D.C. 1991).

Diverse and Skilled Legal Services:

- *Health law practice*–Legal audits and protection of all aspects of practice, including practitioner discipline, licensure, credentialing, malpractice, insurance and Medicare claims, fraud and abuse, Stark and anti-kickback requirements, practice management; drug, medical device, dietary supplement, food labeling, and laboratory regulation; HIPAA privacy regulations; practice purchase; vaccine injury claims; extensive knowledge of medical practice and health care policy issues focusing on complementary and alternative medicine, including clinical delivery issues, managed care, and mental health care issues.
- *Diverse practice*–Transactional, litigation and appellate practice covering tort and contract matters; trademark, business development, employment discrimination, real estate, insurance, criminal matters, attorney sanctions.
- Extensive *litigation* and *appellate* experience as lead/sole counsel before the U.S. Supreme Court, federal and state trial and appellate courts, including full evidentiary hearings before medical boards, other administrative bodies.
- *Solo Practitioner with Firm Experience* – Co-managed cases with Anderson, Kill, Olich & Ochinsky; Sidley & Austin; four years with Swankin & Turner.
- *Obtain Results* – Obtain results, including insurance and other awards, including $250,000 contested award for vaccine-related injury.

LEADERSHIP CONTRIBUTIONS TO DEVELOPMENT IN THE FIELD

Notable Achievement: Acknowledged by White House Commission on Complementary & Alternative Medicine Policy for contributions to Final Report.

- Extensive *pro bono* contributions to the CAM community, organizations and practitioners, such as legislative efforts on conversion of Office of Alternative Medicine at NIH to the National Center for Complementary and Alternative Medicine.
- Represented numerous professional CAM professions before National Center for Vital Health Statistics seeking improved coding of CAM services.
- Co-Chairman, Design Principles for Healthcare Renewal Working Group, a project of the Collaboration for Healthcare Renewal Foundation/ Integrative Medicine Leadership Summit.
- Executive Committee Member, Integrated Healthcare Policy Consortium, the group that created National Policy Dialogue between 60 universities, conventional and CAM professional organizations.
- Developing integrative methodology based on over 100 hours of facilitation of volunteer integrative clinical meetings reviewing cases with acupuncturists, chiropractors, homeopaths, nurses, nutritionists, physicians from various specialties, psychologists, and others.
- Taught integrative methods to Washington, D.C. CAM practitioner network.
- Serve(d) on numerous boards of advisors for CAM programs.

LOBBYING SKILLS

Notable Achievement: Successfully achieved changes in legislative history of the *Health Insurance Portability and Accountability Act of 1996* (HIPAA) to protect the practice of complementary/alternative medicine and physician autonomy.

- Drafted and successfully lobbied in the District of Columbia for the *Qualified Massage Therapists Act of 1994*; assisted in regulatory development of Act.
- Currently working toward legislative protection in Maryland for physicians practicing CAM methods.
- Testimony before FDA, HHS committees on health and food and drug issues.

SUBSTANTIVE EXPERTISE

Notable Experience: Former Director and General Counsel, National Commission for the Certification of Acupuncturists and Oriental Medicine.

- Strong substantive knowledge of *medicine* and *alternative health care* legal, clinical and practice management matters.
- Experienced provider of individual and family therapy; *expertise in psychiatric* and *psychotherapeutic matters.*
- Post-graduate training in *research methods* and *experimental design*.

TEACHING EXPERIENCE

Adjunct Professor: American University—Department of Justice, Law & Society; undergraduate courses in juvenile law, violence in America, and criminal behavior.

- Workshops offered to general public on "How to Choose and Work with an Alternative Practitioner," courses on meditation and other topics.
- Training for CAM practitioners in Alternative Medicine Referral Service.
- Guest lecturer at Capital University of Integrative Medicine.

CLINICAL EXPERIENCE

- Led volunteer bimonthly multidisciplinary clinical meeting, including various medical specialists and acupuncturists, chiropractors, energy workers, massage therapists, mental health practitioners, naturopaths, nurse practitioners, and others to learn clinical aspects of integrative care; provided consultations for selected patients as learning exercise; produced clinical grand round presentation and draft guidelines for integrative clinical practice.
- Lead mental health treatment team staffed by psychiatrist, other therapists.
- Delivered family therapy services to over 500 families, individual and couples therapy to numerous clients; facilitated group psychotherapy, working groups.
- Worked closely on clinical issues with acupuncturists, chiropractors. homeopaths, nutritionists, holistic physicians and other practitioners.

CONSULTING SKILLS

Working with an on-call team of medical and complementary providers as well as research, managed care, insurance and health policy professionals; offering consultation services to care providers regarding:

- · Legal/Regulatory Compliance
- · Board Discipline
- · Billing, Coding, and Documentation
- · Reimbursement Maximization
- · Outcomes Research
- · Risk Management
- · Clinical Integration
- · Credentialing
- · HIPAA Privacy
- · Practice Management
- · Research Methods
- · Network Development
- · Business Development
- · Provider Education

PUBLICATIONS

Forthcoming Books:

- *The Complementary and Alternative Medicine Credentialing Reference Guide* (projected publication TBD).
- *The Coming Wave: A Practical Look at The Integration of Complementary and Alternative Approaches In Medical Settings* (projected publication TBD).

Chapters in Anthologies:

- *Barriers to Accessing Complementary and Alternative Cancer Treatments*, in Complementary and Alternative Therapies in Cancer, Micozzi, M. (ed.), Harcourt Health Sciences (forthcoming July, 2004).
- *Legal and Ethical Issues in Integrative Practice*, in Integrative Medicine, Ben Kligler, M.D., M.P.H. and Roberta Lee, M.D., McGraw-Hill (eds. Beth Israel Medical Center) (forthcoming Spring, 2004).
- *Complementary and Alternative Medicine,* Best Practices in Medical Management, Kongstvedt and Plocher (eds.), Aspen Press (Fall, 1998).
- *Chiropractic and the Law*, Current Controversies in Chiropractic, Redwood (ed.) Churchill-Livingstone (1997)(2nd edition forthcoming Winter of 2003).

Published Articles (note that ACM titles refer to Alternative/Complementary Medicine):

- Dumoff, A. *Interview with Michael Cohen, JD, MBA, MFA.* Alternative/ Complementary Therapies 2003 10(1):TBD.
- Dumoff, A. *Squandering the Promise of Collaboration:Invoking the Tower of Babel By Using and Touting Unproven Therapies,* Alternative/Complemtary Therapies 2003; 9(5):TBD.
- Dumoff, A. *Legal Obstacles to Integrative Practice*, Seminars in Integrative Medicine, Elsevier Publishing (forthcoming, January, 2004).
- Dumoff, A. *Where the Danger Lies: The Imposition of Informed Consent as a Bias in Physician Regulation,* Alternative/Complementary Therapies 2003; 9(5):268-273.
- Dumoff, A. *Left to Our Own Devices? Understanding the Ill-Fitting Nature of BioEnergy Product Regulation,* Alternative/Complementary Therapies 2003; 9(3):202-207.
- Dumoff, A. *National Developments in ACM Policy: A Report on a Maturing Field,* Alternative/Complementary Therapies 2003; 9(2):93-97.
- Dumoff, A. *ACM: An International Perspective*, Alternative/Complementary Therapies 2003; 9(1):45-48.
- Dumoff, A. *Minimizing Malpractice Risk (A Review)*, Integrative Medicine Consult 2002;4(8):88-89.

- Dumoff, A. *Coding System for Alternative and Complementary Therapies: It's Not as Easy as ABC,* Alternative/Complementary Therapies 2002;8(4):246-252.
- Dumoff, A. *New Codes for CAM: HHS Review Could Make Them A Reality*, Alternative Therapies in Health and Medicine 2002; 8(4):32-36.
- Dumoff, A. *The Federation of State Medical Boards' New Guidelines for ACM Practice: Improvements and Concerns* Alternative/Complementary Therapies 2002;8(5):303-309.
- Dumoff, A. *New FSMB CAM Guidelines: Significant Steps in the Right Direction*, The Integrative Medicine Consult 4(9):97, 102-103.
- Dumoff, A. *Protecting ACM Physicians from Undeserved Discipline: Legislative Efforts in Maryland,* Alternative/Complementary Therapies 2002;8-2:120-126.
- Dumoff, A. *A Collision Between Principles and Law: A Case Study in Why Integration is So [Damn] Difficult,* Alternative/Complementary Therapies 2002;8:(1):8-9.
- Dumoff, A. *Is It Merck or is it Pharmanex? The Regulatory Tale of Lovastatin and Cholestin,* Alternative/Complementary Therapies 2001;7(5):310-314.
- Dumoff, A. *Legal Aspects of Integrative Medicine: A Brief Look at LifeWorks Wellness Center,* Alternative/Complementary Therapies 2001;7(4):244-245.
- Dumoff, A. *Creating the New Medicine: Harmonizing Diverse Viewpoints*, Alternative/Complementary Therapies 2001;7(3):174-179.
- Dumoff, A. *Balancing Experience Versus Paradigm: Moving Toward the New Medicine*, Alternative/Complementary Therapies 2001;7(2):112-116.
- Dumoff, A. *An Open Letter to the White House Commission of Complementary and Alternative Medicine Policy, Part 1: Suggestions for Federal Policy & Part 2: Suggestions for State Policy*, Alternative/ Complementary Therapies 2000;6(5):249-257 & 6(6):355-357.
- Dumoff, A. *State Medical Board Prohibitions on Physician Sale of Supplements,* Physician Consult, Fall, 2000.
- Dumoff, A. *Medical Board Prohibitions Against Physician Supplement Sales,* Alternative/Complementary Therapies 2000;6(4):226-236.
- Dumoff, A. *CPT Coding for ACM Services: A Short Course,* Alternative/ Complementary Therapies 2000;6(3):152-161.
- Dumoff, A. *Defining"Disease:" The Latest Struggle for Turf in Dietary Supplement Regulation*, Alternative/Complementary Therapies 2000;6(2):95-104.
- Dumoff, A. *Regulating Professional Relationships: Kickback and Self-Referral Restrictions on Collaborative Practice*, Alternative/Complementary

- Dumoff, A. *Understanding the Kassebaum-Kennedy Health Care Act: Addressing Legitimate Concerns and Irrational Fears*, Alternative/ Complementary Therapies 1997;3(4):309-313.
- Dumoff, A. *Legislation versus Self-Regulation in the Somatic Practices Field: Comments from the Editor*, Alternative/Complementary Therapies 1997;3(3):220-222.
- Dumoff, A. *Expanding the Office of Alternative Medicine into the Center for Integrative Medicine and Creating Access to Medical Treatment; Two Agendas for the 105th Congress*, Alternative/ Complementary Therapies, 1997;3(1): 59-63.
- Dumoff, A. *Protecting Your Practice: Myth v. Fact*, Alternative/ Complementary Therapies 1996;2(3):186-191.
- Dumoff, A. *Malpractice Liability of Alternative/Complementary Health Care Providers: A View From the Trenches*, Alternative/Complementary Therapies, 1995;(1(4):248-253 & 1(5):333-334.
- Dumoff, A. *Including Alternative Providers in Managed Care—Managing the Malpractice Risk (Part I & II)*, Medical Interface (May & June, 1995).
- Dumoff, A. *Private Right of Action*, Administrative Law, Stein, *et al.* (1987).

Former Editorial: Senior Professional Editor, legal/business section IntegrativMedicine (http://www.onemedicine.com).

- Editorial Board, The Integrator: for the Business of Alternative Medicine, IMC Publishing.
- Editorial Board, Journal of Alternative & Complementary Therapy, Liebert Publishing.

CONFERENCE CO-CHAIRMANSHIPS AND PRESENTATIONS

National conferences on alternative medicine, health law topics, including—

- "Credentialing & Legal Issues," Pre-Conference at *Second Annual Integrative Medicine for Healthcare Organizations* co-sponsored by American Hospital Association/Heath Forum and InnoVision Communications, LLC San Diego, (scheduled, January, 2004).
- "Separating Promising Therapies from Wishful Thinking: Choosing and Working with CAM Practitioners: A Professional and Patient-Centered Perspective," *Mini-Med School, Georgetown Medical Center*, March 2003.
- "Credentialing & Privileging Complementary and Alternative (CAM) Practitioners in Health Organizations," presented with Andrew Sparber, R.N., M.S., C.S. *Integrative Medicine for Healthcare Organizations: Business Strategies, Practical Tools, and Best Practices,* co-sponsored by American Hospital Association/Heath Forum and InnoVision Communications, LLC San Francisco, January, 2003.

- "National Policies and Regulations on Integration," *Integration of CAM and Modern Medicine*, the Islamic Organization for Medical Sciences in collaboration with World Health Organization Eastern Mediterranean Regional Office and the Islamic Educational, Scientific and Cultural Organization, Cairo, Egypt, October, 2002.
- Conference Co-chair, *Fourth Annual Congress on Complementary & Alternative Medicine*; Plenary Panel Moderator, "The Complex Patient: Grand Round Case Presentation;" Moderator, "Townhall on Clinical Integration," Panelist, "Provider Networks and Community Integration;" Presenter, "Criminal and Civil Fraud Under Medicare Part B," Arlington, VA, Oct. 1998.
- "Legal and Regulatory Concerns of Providing Alternative Care," *Integrating Alternative & Complementary Medicine with Conventional Medicine,* AIG Conferences, Las Vegas, Sept., 1998.
- "Legal Issues in Health Care Freedom," *Comprehensive Cancer Care: Integrating Complementary and Alternative Therapies*, Center for Mind-Body Medicine, Washington, D.C., June, 1998.
- "Legal and Regulatory Concerns of Providing Alternative Care" and "Clinical Aspects of Alternative Medicine—Designing a Continuum of Care with Allopathic and Alternative Health Care Practitioners," *Integrating Botanicals into Allopathic and Alternative Care,* Institute for International Research, San Francisco, Oct. 1997.
- Conference Co-chair, *Third Annual Congress on Complementary & Alternative Medicine*; Plenary Chair, "The Politics of Alternative Medicine;" Panel Chair, "The Holy Grail: Integrating Alternative and Allopathic Medicine," Arlington, VA, Sept. 1997.
- "Integrating Disparate Practitioners of Care in a Team Practice: Legal and Clinical Considerations," *Integrating Alternative Medicine & Managed Care*, National Managed Health Care Coalition, Philadelphia, Jan. 1997.
- "Legal and Regulatory Concerns of Providing Alternative Care" and "Clinical Aspects of Alternative Medicine–Designing a Continuum of Care with Allopathic and CAM Practitioners," *Developing, Operating and Integrating Complementary Medicine*, AIC Conferences, Atlanta, Nov. 1996.
- "Malpractice and Reimbursement Issues for the Practitioner," *Second Annual Congress of Complementary & Alternative Medicine* Liebert Publishers, Washington, June 1996.
- "Malpractice Liability Imposed Upon Managed Care Organizations: Current Trends and Future Market-Driven Challenges," *Managing Risk: Conference for Managed Care Risk Managers*, AIC Conferences, Chicago, May 1996.

PROFESSIONAL LICENSES

Practice of Law

Maryland, 1988; District of Columbia, 1990; United States District Court for the District of Columbia, 1991; United States Court of Federal Claims, 1991; United States Federal Circuit, 1992; United States Court of Appeals for the District of Columbia, 1992; United States Supreme Court, 1995.

Practice of Social Work

Licensed Graduate Social Worker, Maryland, 1989-1992; 1998 to 2000.

Practice in licensed settings, 1979-83, Michigan, 1984-85, Maryland.

PRACTICE/EMPLOYMENT HISTORY

Solo Private Practice

Washington, D.C., Rockville, MD. August 1992 to present. Represent numerous physicians, acupuncturists, chiropractors, massage therapists, nutritionists and other complementary providers before licensing boards, FDA, HHS, insurance companies, other issues; national organizations on public policy issues; appellate criminal defense work.

LifeTree Consulting/ LifeTree Medical Center, Inc.

Founder and Executive Director. Washington, D.C. August 1993 to present. Start-up health care service which evolved into consulting practice.

Adjunct Professor, American University, Dept. Justice, Law, Society.
Washington, D.C. January 1994 to December 1996. Part-time.

Swankin & Turner, Senior Associate Attorney.
Washington, D.C. October 1988 to August 1992.

Director/General Counsel, National Commission for the Certification of Acupuncturists and Oriental Medicine (during tenure at Swankin & Turner).
Washington, D.C. October 1988 to December 1989.

Stein, Mitchell & Mezines; **Envt'l Protection Agency,** Law Clerk.
Washington, D.C. January 1987 to July 1988; May 1987 to August 1987.

Clinical/Planning Positions, Michigan, Maryland, District of Columbia.

Therapist–Private Clinical Practice; Karma Academy for Boys, Maryland; 1984-1985; Runaway Emergency Action Center and Hotline (REACH), Michigan; Probation Officer, Michigan; 1979-1983, 1984-1985.

Planning Technician—United Way, Michigan; Department of Community Development, Michigan; 1977-1979**.**

EDUCATION

Catholic University School of Law, Juris Doctorate, 1988, top 19 percent. Senior Staff Member, Journal of Contemporary Health Law and Policy; Professorial honors for trial practice; Bamberger Competition semi-finalist; Research Assist., Harold McDougall.

Catholic University School of Social Service, Master of Social Work, 1987. Chair, Alumnae/i Curriculum Committee; Post-grad coursework in experimental design.

University of Michigan, Bachelor of Arts, Clinical/Community Psychology, 1977; Debate competition honors.

Continuing Education:

Law—"The Unexamined Anatomy of the Kassebaum-Kennedy Act," ABA; "Making A Deal with Doctors," ABA; "Consumer Law," D.C. Bar; "Food and Drug Law, Health Claims on Foods," FDLI; "Employment Law," "Counseling Alternative Providers," ABA; "Vaccine Injury Law," U.S. Claims Court; "Medicare Reimbursement Issues," Medical Management Institute; "Appellate Advocacy," Public Defender's Office; "Intellectual Property," D.C. Bar, "Food and Drug Law," D.C. Bar, "Institutional Review Boards," D.C. Bar; "HIPAA Implementation", D.C. Bar; "Administrative Simplification Act Issues," D.C. Bar, numerous other CLE and other seminars.

Health Care—Extensive training and self-education in individual/family therapy, alternative care, medical ethics. Dozens of conferences in addition to those listed under presentations, including "Building Bridges: The Link Between Allopathic and Alternative Medicine in Clinical Practice and Research," Johns Hopkins University and the Traditional Acupuncture Institute; "Credentialing CAM Practitioners," Greeley Consulting; "Alternative Medicine Track" at National Managed Health Care Congress.